

Whereas, immunity under section 319F–3(a) of the Act should be available to governmental program planners for distributions of Covered Countermeasures obtained voluntarily, such as by (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles;

Whereas, the extent of immunity under section 319F–3(a) of the Act afforded to a governmental program planner that obtains Covered Countermeasures except through voluntary means is not intended to affect the extent of immunity afforded other covered persons with respect to such covered countermeasures;

Whereas, to encourage the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures with respect to the category of disease and population described in section II and IV it is advisable, in accordance with section 319F–3(a) and (b) of the Act, to provide immunity from liability for covered persons, as that term is defined at section 319F–3(i)(2) of the Act, and to include as such covered persons such other qualified persons as I have identified in section VI;

Whereas, in accordance with section 319F–3(b)(6) of the Public Health Service Act (42 U.S.C. 247d–6d(b)) (“the Act”), I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures with respect to the category of disease and population described in sections II and IV below, and have found it desirable to encourage such activities for the Covered Countermeasures;

Therefore, pursuant to section 319F–3(b) of the Act, I have determined there is a credible risk that the spread of avian influenza viruses and resulting disease could in the future constitute a public health emergency, and that 2009 H1N1 influenza constitutes a public health emergency.

I. Covered Countermeasures (as Required by Section 319F–3(b)(1) of the Act)

Covered Countermeasures are defined at section 319F–3(i) of the Act.

At this time, and in accordance with the provisions contained herein, I am recommending the manufacture, testing, development, distribution, dispensing; and, with respect to the category of disease and population described in sections II and IV, below, the administration and usage of the pandemic countermeasure influenza A H5N1, H2, H6, H7, H9, and 2009 H1N1 Vaccines and any associated adjuvants. The immunity specified in section 319F–3(a) of the Act shall only be in effect with respect to: Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding for pandemic countermeasure influenza A H5N1, H2, H6, H7, H9, and 2009 H1N1 vaccines used and administered in accordance with this declaration. In accordance with section 319F–3(b)(2)(E) of the Act, for governmental program planners, the immunity specified in section 319F–3(a) of the Act shall be in effect to the extent they obtain Covered Countermeasures through voluntary means of distribution, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles. For all other covered persons, including other program planners, the immunity specified in section 319F–3(a) of the Act shall, in accordance with section 319F–3(b)(2)(E) of the Act, be in effect pursuant to any means of distribution.

This declaration shall subsequently refer to the countermeasures identified above as Covered Countermeasures.

This declaration shall apply to all Covered Countermeasures administered or used during the effective time period of the declaration.

II. Category of Disease (as Required by Section 319F–3(b)(2)(A) of the Act)

The category of disease for which I am recommending the administration or use of the Covered Countermeasures is the threat of or actual human influenza that results from the infection of humans following exposure to the virus with (1) highly pathogenic avian influenza A (H5N1, H2, H6, H7, or H9) virus; or (2) 2009 H1N1 influenza.

III. Effective Time Period (as Required by Section 319F–3(b)(2)(B) of the Act)

The effective period of time of this Declaration commences on December 1, 2006 and extends through February 28, 2010; except that with respect to 2009 H1N1 influenza vaccine, the effective period commences on June 15, 2009 and extends through March 31, 2013.

IV. Population (as Required by Section 319F–3(b)(2)(C) of the Act)

Section 319F–3(a)(4)(A) confers immunity to manufacturers and distributors of the Covered Countermeasure, regardless of the defined population.

Section 319F–3(a)(3)(C)(i) confers immunity to covered persons who could be program planners or qualified persons with respect to the Covered Countermeasure only if a member of the population specified in the declaration administers or uses the Covered Countermeasure and is in or connected to the geographic location specified in this declaration, or the program planner or qualified person reasonably could have believed that these conditions were met.

The populations specified in this Declaration are the following: (1) All persons who use a Covered Countermeasure or to whom such a Covered Countermeasure is administered as an Investigational New Drug in a human clinical trial conducted directly by the Federal Government, or pursuant to a contract, grant or cooperative agreement with the Federal Government; (2) all persons who use a Covered Countermeasure or to whom such a Countermeasure is administered in a pre-pandemic phase, as defined below; and/or (3) all persons who use a Covered Countermeasure, or to whom such a Covered Countermeasure is administered in a pandemic phase, as defined below.

V. Geographic Area (as Required by Section 319F–3(b)(2)(D) of the Act)

Section 319F–3(a) applies to the administration and use of a Covered Countermeasure without geographic limitation.

VI. Other Qualified Persons (as Required by Section 319F–3(i)(8)(B) of the Act)

With regard to the administration or use of a Covered Countermeasure, Section 319F–3(i)(8)(A) of the Act defines the term “qualified person” as a licensed individual who is authorized to prescribe, administer, or dispense the countermeasure under the law of the State in which such Covered Countermeasure was prescribed,